Part IB 2 Labelling and Package Leaflet

A. LABELLING

The packaging text for the carton and immediate label is based on the QRD Template format and does not reflect the order or sequence on the actual labelling and their position or repetition on the individual sides/flaps of the packaging. The boxed headings will not appear in the final printed packaging materials. The proposed labelling text as it will appear on the final packaging materials will be presented at the end of the procedure.

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Genta-Equine 100 mg/ml Solution for Injection.
Gentamicin (as gentamicin sulfate).

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains
Gentamicin (as gentamicin sulfate) 100 mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses (non-food producing horse).

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intravenous use.

8. WITHDRAWAL PERIOD

Do not use in horses which are intended to produce meat or milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in horses which are intended to produce meat or milk for human consumption.

10. EXPIRY DATE

Exp {month/year}
Use broached vial within 28 days
Use by _/_

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable.

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Franklin Pharmaceuticals Ltd
Athboy Road
Trim
Co. Meath
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 33848/4000

17. MANUFACTURER'S BATCH NUMBER

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Genta-Equine 100 mg/ml Solution for Injection.
Gentamicin (as gentamicin sulfate).

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains
Gentamicin (as gentamicin sulfate) 100 mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses (non-food producing horse).

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intravenous use.

8. WITHDRAWAL PERIOD

Do not use in horses which are intended to produce meat or milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in horses which are intended to produce meat or milk for human consumption.

10. EXPIRY DATE

Exp {month/year}
Use broached vial within 28 days
Use by _/_

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable.

For animal treatment only.

17. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

18. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Franklin Pharmaceuticals Ltd
Athboy Road
Trim
Co. Meath
Ireland

19. MARKETING AUTHORISATION NUMBER

Vm 33848/4000

17. MANUFACTURER'S BATCH NUMBER

Package leaflet

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT.

Marketing Authorisation Holder	Manufacturer responsible for batch release
Franklin Pharmaceuticals Ltd Athboy Road Trim Co. Meath Ireland	Divasa Farmavic, SA. Ctra. Sant Hipolit Km Gurb-Vic Barcelone 08503 Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Genta-Equine 100 mg/ml Solution for Injection for Horses.
Gentamicin (as gentamicin sulfate)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains

Gentamicin (as gentamicin sulfate)	100 mg

Excipients:

Sodium Metabisulfite	1.0 mg
Sodium Methyl parahydrxybenzoate (E219)	0.9 mg
Sodium Propyl parahydroxybenzoate	0.1 mg

4. INDICATION(S)

For the treatment of infections of the lower respiratory tract in horses caused by aerobic Gram-negative bacteria susceptible to gentamicin.

5. CONTRAINDICATIONS

Do not use in known cases of renal dysfunction.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
Do not exceed the proposed dosing regimen.

6. ADVERSE REACTIONS

Hypersensitivity reactions have been reported very rarely following the use Genta-Equine 100 mg/ml Solution for Injection for Horses.

A local reaction may occur at the injection site, especially in case of repeated injections in adjacent sites

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses (non-food producing horses).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intravenous use.
Single dose of 6.6 mg/kg body weight given intravenously once daily for 3–5 consecutive days.
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under- or over-dosing. The dosing regimen must not be exceeded.
The use of gentamicin in foals and neonates is not recommended.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage bodyweight should be determined as accurately as possible to avoid under or over dosing.

10. WITHDRAWAL PERIOD

Not authorised for use in horses producing meat or milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last days of that month.
Shelf life after first opening the container: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label and carton.

12. SPECIAL WARNINGS

Special precautions for use in animals

Gentamicin is well known to induce nephrotoxicity even at therapeutic doses. There are also isolated reports of ototoxicity with gentamicin. No margin of safety has been established under the approved dosing regimen. As such, gentamicin has a narrow

margin of safety. The product should therefore only be used based on the benefit-risk assessment by the responsible veterinary surgeon for each individual horse, taking into account alternative available treatment.
In order to reduce the nephrotoxic risk, adequate hydration of animals under treatment should be ensured, and fluid therapy should be instituted, if required.
Close monitoring of horses being treated with gentamicin is strongly advised. This monitoring includes assessing relevant kidney parameters in blood (e.g. creatinine and urea) and urinalysis (e.g. gamma glutamyl transferase/creatinine ratio).
Therapeutic blood monitoring of gentamicin concentration is also recommended because of known individual animal variations in peak and trough gentamicin plasma concentrations. Where blood monitoring is available, target peak plasma gentamicin concentrations should be approximately 16–20 µg/ml.
Particular caution should be taken when administering gentamicin with other potential nephrotoxic medicinal products (containing e.g. NSAIDs, furosemide, and other aminoglycosides).
Safety of gentamicin has not been established in foals and there is a lack of knowledge of the extra effects of gentamicin on foal kidneys, especially neonates. Current knowledge suggests that foals, especially neonates, are at a higher risk of gentamicin-induced nephrotoxicity compared to adults. Differences between neonatal foal kidneys and adults include a slower clearance of gentamicin in foals. As such, no margin of safety has been established in neonatal foals. It is therefore not recommended to use the product in foals.
Whenever possible, use of the product should be based on susceptibility testing of the bacteria isolated from the animal. Gentamicin is a narrow-spectrum Gram-negative bactericidal antimicrobial, without effects on anaerobe bacteria and mycoplasmas. Gentamicin does not penetrate intracellularly, or into abscesses. Gentamicin is de-activated in the presence of inflammatory debris, low oxygen environments and low pH.
The dosing regimen must not be exceeded. Use of the product deviating from the instructions given in the SPC increases the risk of nephrotoxicity, and may increase the prevalence of bacteria resistant to gentamicin.
Extra caution is advised if using gentamicin in old horses, or with fever, endotoxemia, sepsis and dehydration.
Pregnancy:
The safety in pregnant horses is unknown. However, studies in laboratory animals have shown evidence of fetal nephrotoxicity. Use only based on the benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Gentamicin may cause hypersensitivity (allergic) reactions following exposure. People with known hypersensitivity to gentamicin should avoid contact with the product.
Administer the product with caution.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy and lactation

Do not use in pregnant animals.

Interaction with other medicinal products and other forms of interaction

This product should not be used in conjunction with other aminoglycoside antibiotics, or with other drugs known to induce either ototoxicity or nephrotoxicity.

Overdose (symptoms, emergency procedures, antidotes), if necessary.

The product was not specifically tested in overdose studies and therefore, no margin of safety has been determined.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED.

15. OTHER INFORMATION.

Gentamicin sulfate is poorly absorbed from the gastrointestinal tract thus the product must be administered parenterally for systemic action. It appears in the synovial and peritoneal fluids but effective levels are not reached in CSF, bronchial secretions, ocular fluids or milk. Elimination is mainly by glomerular filtration and it rapidly appears in the urine.

Gentamicin is a highly polar drug with poor tissue penetration; it distributes mainly into extracellular fluids.

Legal category

POM-V

Marketing authorisation number

Vm No: 33848/4000

Package quantity: 100 ml

Company logo

Approved: 06 February 2019

D Austin